510(k) Summary

for

NovoPore™ Dressing

1. Submission Sponsor

PolyNovo Biomaterials Pty Ltd
2/320 Lorimer St
Port Melbourne, 3207
Victoria
Australia
Phone: 613 8681 4086
Fax: 613 8681 5099
Contact: Dr. Tim Moore, Principal Scientist

2. Submission Correspondent

Emergo Group
816 Congress Avenue, Suite 1400
Austin, TX 78701
Cell Phone: (720) 838.4113
Office Phone: (512) 327.9997
Fax: (512) 327.9998
Contact: Carrie Hetrick, Senior Consultant, RA
Email: project.management@emergogroup.com

3. Date Prepared

February 25, 2014

4. Device Identification

Trade/Proprietary Name:	NovoPore™ Dressing
Common/Usual Name:	Negative Pressure Wound Therapy Foam
Classification Name:	Negative Pressure Wound Therapy Powered Suction Pump and Accessories
Classification Regulation:	878.4780
Product Code:	OMP
Device Class:	Class II
Classification Panel:	General and Plastic Surgery

5. Legally Marketed Predicate Device(s)

Kinetic Concepts, Inc. (KCI) GranuFoam®, 510 (k) Number K032310
Genadyne Biotechnologies, Inc. A4-XLR8 Foam Dressing, 510 (k) Number K092992

6. Device Description

The NovoPore™ Dressing is a polyurethane foam wound dressing used as an accessory to powered suction pumps. The single-use dressing is packaged in a peelable oriented polyamide / polyethylene bag and is sterilized by gamma irradiation.

The NovoPore™ Dressing is available in one size: medium.

7. Indication for Use Statement

NovoPore™ is intended to be used as part of a Negative Pressure Wound Therapy (NPWT) system. When used in conjunction with a NPWT system, it is intended to remove excess exudate, infectious material, and tissue debris from wounds which may promote wound healing. NPWT systems are indicated for use on chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), explored fistulas, flaps, and grafts.

8. Substantial Equivalence Discussion

The following table compares the NovoPore™ Dressing device to the predicate devices with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5A – Comparison of Characteristics

Device Manufacturer	**PolyNovo Biomaterials Pty Ltd**	**Kinetic Concepts, Inc. (KCI)**	**Genadyne Biotechnologies, Inc.**
Device Trade Name	**NovoPore™ Dressing**	**GranuFoam™**	**A4-XLR8 Foam Dressing**
510(k) Number	K132936	K032310	K092992
Regulation Number	878.4780	878.4780	878.4780
Product Code	OMP	OMP	OMP
Common/Usual Name	Negative Pressure Wound Therapy Foam	Negative Pressure Wound Therapy Foam	Negative Pressure Wound Therapy Foam
Regulation Name	Negative Pressure Wound Therapy Powered Suction Pump and Accessories	Negative Pressure Wound Therapy Powered Suction Pump and Accessories	Negative Pressure Wound Therapy Powered Suction Pump and Accessories
Indications for Use	NovoPore™ is intended to be used as part of a Negative Pressure Wound Therapy (NPWT) system. When used in conjunction with a NPWT system, it is intended to remove excess exudate, infectious material, and tissue debris from wounds which may promote wound healing. NPWT systems are indicated for use on chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness	The V.A.C.® family of devices are feedback-controlled negative pressure devices used to help promote wound healing, through means including vacuum assisted drainage and removal of infectious material or other fluids, under the influence of continuous and/or intermittent suction pressures, particularly for patients with chronic, acute, traumatic, subacute and	Genadyne A4-XLR8 Foam Dressing is intended to be used in conjunction with the Genadyne A4 Wound Vacuum System (K082676) to deliver negative pressure wound therapy to the wound. Genadyne A4 Wound Vacuum System is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing by the removal of

Device Manufacturer	PolyNovo Biomaterials Pty Ltd	Kinetic Concepts, Inc. (KCI)	Genadyne Biotechnologies, Inc.
Device Trade Name	**NovoPore™ Dressing**	**GranuFoam™**	**A4-XLR8 Foam Dressing**
	burns, ulcers (such as diabetic or pressure), explored fistulas, flaps, and grafts.	dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts. Feedback control is achieved by measuring the level of negative pressure at the wound site.	excess exudates, infectious material and tissue debris. A4-XLR8 Foam Dressing is appropriate for use on the following wounds: • Pressure ulcers • Diabetic/Neuropathic Ulcers • Venous insufficiency ulcers • Traumatic wounds • Post-operative and dehisced surgical wounds • Comparative Bench Caution: Federal law restricts this device to sale by or on the order of a physician.
Dressing Composition	Porous, open-celled polyurethane foam	Porous, open-celled polyurethane foam	Porous, open-celled polyurethane foam
Form	Foam	Foam	Foam
Material	Polyurethane	Polyurethane	Polyurethane
Method to achieve Open-Celled Foam	Crushing the foam	Reticulating the foam	Reticulating the foam
Color	White	Black	Green
Dimensions (medium), cm	18 x 12.5 x 3	18 x 12.5 x 3.2	18 x 12.5 x 3.3
Recommended pressure range (mmHg)	-50 to -175	-125 plus or minus increments of 25-75 as needed, up to -250.	-50 to -230
Cyclic compression – Mean Upper Compressive Stress and Standard deviation at 0, 1, 2, 4 and 6 hours, wet	0 min: 20.7±3.2 kPa 1 hr: 21.4 ±3.4 kPa 2 hrs: 20.3±3.4 kPa 4 hrs: 18.0 ± 2.7 kPa 6 hrs: 17.2±2.3 kPa	0 min: 13.4±0.4kPa 1 hr: 12.5 ±0.6 kPa 2 hrs: 12.8±0.9 kPa 4 hrs: 13.4 ± 1.0 kPa 6 hrs: 13.9 ±1.1 kPa	0 min: 12.8±1.3 kPa 1 hr: 11.5 ±0.9 kPa 2 hrs: 11.6±0.9 kPa 4 hrs: 12.0 ± 1.0 kPa 6 hrs: 12.6± 1.2 kPa
Cyclic compression – Resilience change at 0, 1, 2, 4, and 6 hours, wet	0 min: 0.0± 0 % 1 hr: 2.0 ± 0 % 2 hrs: 2.0± 0 % 4 hrs: 2.0± 0 % 6 hrs: 2.0± 0 %	0 min: 0.0± 0 % 1 hr: 8.9 ±1.6 % 2 hrs: 10.3± 1.6 % 4 hrs: 12.3 ± 2.1 % 6 hrs: 14.2 ± 2.2 %	0 min: 0.0± 0 % 1 hr: 10.3 ± 1.2 % 2 hrs: 11.9 ± 1.4 % 4 hrs: 14.4 ± 2.1 % 6 hrs: 16.7± 3.1 %
Mean Change in Thickness after 6 hours, wet (1350 cycles)	Decrease by an average of 1.5 ± 0.5%	Decrease by an average of 7.6 ± 2.6%	Decrease by an average of 8.0 ± 2.4%

Device Manufacturer	PolyNovo Biomaterials Pty Ltd	Kinetic Concepts, Inc. (KCI)	Genadyne Biotechnologies, Inc.
Device Trade Name	NovoPore™ Dressing	GranuFoam™	A4-XLR8 Foam Dressing
Durability after 1350 compressive cycles, wet	No Damage	No Damage	No Damage
Vacuum Bench Test – Pressure distribution	Evenly Distributed at each time point	Evenly Distributed at each time point	Not Tested
Vacuum Bench Test – Fluid Flow (T=0, 24h, 48h, 72h)	25 ml fluid drawn through within 30 seconds at every time point	25 ml fluid drawn through within 30 seconds at every time point	Not Tested
Vacuum Bench Test – Dimensional change after 72h	<10% change in dimensions	<10% change in dimensions	Not Tested
Tensile Strength	223 ± 17 kPa	105 ± 13 kPa	Not Tested
Tensile Elongation at Break	225 ± 11 %	185 ± 24	Not Tested
Tear Strength	399 ± 32	733 ± 76	Not Tested
Foam Density	66.1 kg/m³	23.0 kg/m³	21.1 kg/m³
Open Pore Size	100 – 600 microns	400 – 600 microns	Not available
Single-Use	Yes	Yes	Yes
Supplied Sterile	Yes	Yes	Yes
Sterilization Method	Gamma Irradiation	Gamma Irradiation	EO
Shelf Life	Two (2) years	Three (3) years	Three (3) years

9. Non-Clinical Performance Data

Mechanical properties of NovoPore™ Dressing were evaluated and compared with the predicates V.A.C. GranuFoam™ Dressing and A4-XLR8 Foam Dressing. The following testing has been performed to support substantial equivalence:

- Biocompatibility – Biocompatibility testing of the NovoPore™ Dressing was conducted in accordance with the ISO 10993-1 "Biological evaluation of medical devices" standards and FDA/CDRH/ODE Blue Book Memorandum G95-1, "Use of International Standard ISO 10993", 'Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing' using a representative device. Based on ISO 10993-1, NovoPore™ Dressing is intended for use in direct contact with wounds, and the finished device is used in the human body for 24 (twenty-four) hours to 30 (thirty) days. The NovoPore™ Dressing was tested for Cytotoxicity per ISO 10993-5; Mutagenicity (In Vitro Mouse Lymphoma Assay) per ISO 10993-3; Bacterial Reverse Mutation (AMES test) per ISO 10993-3; Intracutaneous Reactivity, Skin Sensitisation (polar and non-polar) per ISO 10993-1, ISO 10993-10, and ISO 10993-12; per ISO 10993-1; Subcutaneous implantation per ISO 10993-1, ISO 10993-6, and ISO 10993-12; and Pyrogenicity per Ph. Eur. 7th edition. The results for the biocompatibility testing showed that there are no negative impacts from materials that are used in the NovoPore™ Dressing.

- Shelf-life – Stability of the subject device was established from the results of physical testing data using a protocol. Based on the evaluation of the results of the physical

testing data, the expiring date has been set at two (2) years in accordance with ISO 11607 and ASTM F1980-07.

- Package Stability - Based on the results, these tests confirm the sealing and seal system (selection of materials) of the tested packages are suitable to maintain the integrity and therefore the microbial barrier of packages for medical devices as required by ISO 11607-1. LAL testing is routinely used to verify acceptable low levels of endotoxin contamination per AAMI ST72.

- Mechanical testing -The tests involved cyclic compressive stress at various time points, resilience under cyclic compressive testing, durability under accelerated cyclic compression, and performance under vacuum, testing. It was concluded that the NovoPore™ Dressings met all acceptance criterion for Mean USC, Mean SZL, and Mean percentage Change in Thickness, and degree of damage, hence are substantially equivalent to GranuFoam™ and XLR8 in terms of cyclic mechanical properties. It was also concluded that the NovoPore™ dressings showing substantially similar performance to GranuFoam dressings during and after the 72 hours of 17 kPa vacuum non-clinical bench testing.

- Risk Management – Risk Analysis was conducted according to ISO 14971, and the outcomes of these risks are considered acceptable, and that all potential risks have been mitigated to the lowest form.

As part of demonstrating safety and effectiveness of NovoPore™ Dressing and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, PolyNovo Biomaterials Pty Ltd completed a number of tests. The NovoPore™ Dressing meets all the requirements for overall design, sterilization, and biocompatibility confirms that the output meets the design inputs and specifications. The NovoPore™ Dressing passed all testing stated above as shown by the acceptable results obtained.

The NovoPore™ Dressing complies with the applicable voluntary standards for biocompatibility and sterilization. The device passed all the testing in accordance with national and international standards.

10. Clinical Performance Data

Human clinical trials are not applicable as there are no new innovative aspects that have been introduced. These types of products have been on the market for many years with no significant incidents of safety or efficacy for the predicate devices. The design, development and testing of the NovoPore™ Dressing has not resulted in the need for any clinical trials.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the

predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the difference between the NovoPore™ Dressing and the predicate devices do not raise any questions regarding its safety and effectiveness. The NovoPore™ Dressing, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 4, 2014

PolyNovo Biomaterials Pty Ltd
% Ms. Carrie Hetrick
Emergo Group
816 Congress Avenue, Suite 1400
Austin, Texas 78701

Re: K132936
Trade/Device Name: NovoPore Dressing
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: January 30, 2014
Received: January 31, 2014

Dear Ms. Hetrick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita Ashar, MD, MBA, FACS
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132936

Device Name
NovoPore™ Dressing

Indications for Use *(Describe)*
NovoPore™ is intended to be used as part of a Negative Pressure Wound Therapy (NPWT) system. When used in conjunction with a NPWT system, it is intended to remove excess exudate, infectious material, and tissue debris from wounds which may promote wound healing. NPWT systems are indicated for use on chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), explored fistulas, flaps, and grafts.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

David Krause -S